

REMARKS

Claim Amendments

Claims 1-9 are pending in this application. Applicants have amended claim 1 to improve its form. The above amendment does not add new matter. Applicants request entry of the amendment.

Obviousness-Type Double Patenting

Claims 1-9 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over co-pending United States Application 10/555,038 in view of Cham et al. (U.S. Patent 5,958,770) (Cham) and Schmidt et al. (U.S. Patent 6,242,583) (Schmidt). Applicants request that this rejection be held in abeyance until allowable subject matter is found in the instant application and the '038 application. Applicants will then deal with the obviousness-type double patenting rejection in the appropriate way.

Rejection under 35 U.S.C. § 102(b)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Cham. The Examiner contends that Cham refers to a derivative of a glucose-solasodine conjugate.

Applicants traverse. A claim is anticipated “only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”

MPEP § 2131.01. Claim 1 refers to a glucose-solasodine conjugate “wherein each of R₁ and R₂ are the same or different and represents a benzoyl or a pivaloyl group.” The Examiner acknowledges that Cham does not “disclose glucose-solasodine conjugates wherein the glucose

moiety is substituted by benzoyl or a pivaloyl group” (Office Action, p. 3). *See also* Cham, col. 4, lines 18-20. Accordingly, claim 1 is not anticipated by Cham. Applicants request reconsideration and withdrawal of this rejection.

Rejections under 35 U.S.C. § 103(a)

Claim 1 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Schmidt. The Examiner contends that Cham refers to glucose conjugates of solasodine wherein the hydroxyl groups are substituted by acetyl groups, and that Schmidt teaches the conventional use of acetyl, benzoyl, and pivaloyl groups in sugar synthesis. The Examiner concludes that the skilled artisan at the time the invention was made would have been motivated to substitute a benzoyl or pivaloyl group for the acetyl group in the compound referred to in Cham to produce the compound of the claimed invention. Applicants traverse.

This application describes glucose-solasodine conjugates in which the hydroxyl groups are substituted by benzoyl and pivaloyl groups, wherein said conjugates are advanced intermediates in solamargine or solasonine synthesis. Neither Cham nor Schmidt, alone or in combination, refers to solamargine or solasonine synthesis. Indeed, among Cham’s preferred compounds are solasonine and solamargine themselves. *See, e.g.*, col. 4, lines 23-24. For this reason alone, the skilled artisan at the time the invention was made would have had no motivation and the art would have provided no suggestion to substitute a benzoyl or pivaloyl group, as allegedly referred to in Schmidt, for the acetyl group in the compound allegedly referred to in Cham. Accordingly, claim 1 is not obvious over Cham in view of Schmidt.

Claims 2 and 4-7 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Holick (U.S. Patent 5,612,317) (Holick) and Schmidt. The Examiner contends

that Cham refers to glucose conjugates of solasodine and that Holick refers to a conventional method for glycosylating a closely analogous steroid derivative by reacting the steroid with a protected sugar donor. The Examiner further contends that Schmidt refers to the conventional use of acetyl, benzoyl, and pivaloyl protecting groups in sugar synthesis. The Examiner concludes that one of ordinary skill at the time the invention was made would have been motivated to prepare glucose-solasodine conjugates referred to in Cham using the glycosylation method referred to in Holick and the conventional protecting groups referred to in Schmidt. Applicants traverse.

This application describes a method for the preparation of glucose-solasodine conjugates as advanced intermediates in solamargine or solasonine synthesis. Cham, Schmidt and Holick, alone or in combination, do not refer to methods of solamargine or solasonine synthesis. Therefore, even with these documents in hand, the skilled artisan at the time the invention was made would have had no motivation and been provided no suggestion to use the method allegedly referred to in Holick, or to select an acetyl, benzoyl or pivaloyl group, as allegedly referred to in Schmidt, to prepare a glucose-solasodine conjugate, as allegedly referred to in Cham. Accordingly, claim 2 and dependent claims 4-7 are not obvious over Cham in view of Holick and Schmidt.

Claims 3, 8 and 9 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Cham in view of Ohira et al. (U.S. Patent 6,084,081) (Ohira). The Examiner states that Cham refers to solamargine and glucose-solasodine conjugates and that glycosylation of a sugar moiety was well known in the art, as referred to by Ohira, at the time the invention was made. The Examiner concludes that the skilled artisan at the time the invention was made would have been

motivated to use a method of glycosylation of a sugar moiety, as referred to by Ohira, to glycosylate a glucose-solasodine conjugate, as referred to by Cham, to prepare solamargine, as referred to by Cham. Applicants traverse.

Neither Cham nor Ohira are directed to methods of solamargine or solasonine synthesis. Therefore, even with these documents in hand, the skilled artisan at the time the invention was made would have had no motivation and been provided no suggestion to use the method allegedly referred to in Ohira to prepare solamargine as allegedly referred to in Cham. Further, neither Cham nor Ohira refers to **specific** techniques to add further sugar molecules to solasodine-glucose conjugates in order to produce solamargine or solasonine. Therefore, based on those doubts, the skilled artisan would not have had a reasonable expectation of success in using the teachings of these documents, alone or in combination, to successfully synthesize solamargine or solasonine. Accordingly, claim 3 and dependent claims 8 and 9 are not obvious over Cham in view of Ohira.

In summary, the present application describes the **total** and **specific synthesis** of solamargine and solasonine. Cham allegedly refers to these compounds, but is not directed to the synthesis of solamargine or solasonine or the preparation of advanced intermediates in the synthesis of solamargine or solasonine. Schmidt, Holick and Ohira allegedly refer to the use of protecting groups in the synthesis of carbohydrate molecules. However, even with these documents in hand, one skilled in the art at the time the invention was made would have had no guidance in selecting specific protecting groups to protect a hydroxyl group in the intermediate stages of solamargine or solasonine synthesis. None of the cited documents, thus, discloses or makes obvious the **specific task** of synthesizing solamargine or solasonine. Accordingly, claims

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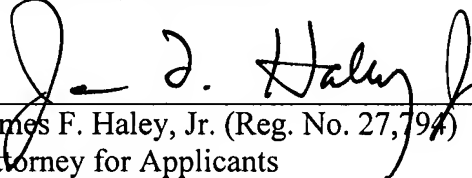
1-9 are not obvious over the cited documents. Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

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CONCLUSION

Applicants request favorable consideration and early allowance of the elected claims.

Respectfully submitted,



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